Supreme Court, U.S.
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IN THE

Supreme Court of the United States

October Term, 1994

LINDA L. McCUMMINGS,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Keith W. Donahoe, Esq.
KOONZ, MCKENNEY, JOHNSON & REGAN, P.C.
2020 K Street, N.W.
Suite 840
Washington, D.C. 20006
(202) 659-5500

Attorney for Petitioner

CASILLAS PRESS, INC., 1717 K STREET, N.W., WASHINGTON, D.C. 20036

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QUESTION PRESENTED

To prevail under the National Vaccine Injury Act, must a Petitioner with an off-Table injury prove within scientific certainty that her injuries were caused by a vaccine or is it sufficient for such a Petitioner to show that her injuries were more likely than not the result of a vaccine?

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The plaintiff-appellant below, Linda L. McCummings, petitions for a writ of certiorari to review the judgment of the United States Court of Appeals For The Federal Circuit.

OPINIONS BELOW

The special master's order, (App. 1-30), denying plaintiff's petition for compensation is unreported. Judge Robinson's opinion (App. 31-46), upholding the special master's decision, is reported at 27 Cl. Ct. 417 (1992). The decision of the U.S. Court of Appeals for the Federal Circuit, (App. 45-51), upholding Judge Robinson's decision is unreported.

JURISDICTION

The judgment of the court of appeals (App. 47-51), was entered on November 23, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. §1254.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The National Childhood Vaccine Injury Act, 42 U.S.C. 300 et. seq.

STATEMENT OF THE CASE

Heather McCummings was born on July 21, 1980, without complications. On February 16, 1981, Heather received her second set of Diphtheria-Pertussis-Tetanus (hereinafter DPT) and Oral Polio Vaccine (hereinafter OPV) vaccinations. Just five days after receiving the inoculations, Heather could no longer move her legs or sit up.

Two days after the on-set of her symptoms, on February 23, 1991, Heather was admitted to the hospital, where a neurologist, Dr. Douglas Abbott, diagnosed Heather's condition as "transverse myelitis,[1] secondary to inoculations." (App. at

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[1]Transverse Myelitis is a disorder of the spinal cord characterized by its sudden onset of symptoms which include paralysis of the lower extremities, loss of bladder control, and severe back pain. The cause of the condition is generally considered to be an autoimmune response to a variety of

(continued...)

3). Over the following eight days, Heather received a comprehensive examination which confirmed Dr. Abbott's diagnosis of transverse myelitis. Significantly, the hospital stay included an examination by Dr. Margaret Rennels, an infectious disease specialist present to examine Heather for signs of viral infection; Dr. Rennels failed to make any findings of symptomology consistent with a possible viral agent as the cause of Heather's transverse myelitis. (App. at 4).

Over the next few months, Heather underwent comprehensive and thorough examinations at a variety of medical institutions which failed to reveal any possible cause of the transverse myelitis except the associa-

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[1](...continued)
pathogens which include rabies vaccine, smallpox vaccine, polio, measles, and mononucleosis. The disorder has been shown to incur in all age groups but is rarer in children with an incident rate as small as 1:1,000,000 individuals.

tion with the immunizations. In light of the clear temporal association between the transverse myelitis and the vaccinations, various physicians opined that Heather should not receive any further pertussis or live polio vaccines.

In 1986, Congress passed the National Vaccine Injury Act (hereinafter The Vaccine Act) establishing a system to provide compensation to individuals who were injured as the result of a vaccination.[2] On September 10, 1990, Linda McCummings filed a petition for compensation under the Vaccine Act on behalf of her daughter, Heather McCummings.

On April 16, 1992, a hearing was held before Chief Special Master Gary J. Golkiewicz at which Dr. Shlomo Shinnar, an expert with over 15 years experience in

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[2] 42 U.S.C. 300aa-11(a)(1) (providing the United States Claims Court with jurisdiction over matters arising under the Vaccine Act).

pediatric neurology, testified on behalf of the petitioner. Dr. Shinnar testified that, in his opinion, the vaccinations were more likely than not the cause of Heather's transverse myelitis. By a decision dated July 10, 1992, the Chief Special Master denied the petitioner's request for compensation. (App. at 1).

In setting forth his reasons for denying the petition, the Chief Special Master stated that he found that the Petitioner failed to show "an actual causal link between the vaccination and the injury." (App. at 30). Because the Special Master utilized an incorrect standard regarding petitioner's burden of proof, the Petitioner filed for review by the Federal Court of Claims.

On December 23, 1992, Judge Wilkes C. Robinson affirmed the Special Master's denial of Petitioner's claim, stating that

the Special Master denied Petitioner's claim because the Petitioner "failed to meet her burden of proof [in failing to] demonstrate that the vaccinations caused Heather's transverse myelitis." (App. at 43).

The Petitioner then filed an appeal of Judge Robinson's decision with the United States Court of Appeals for the Federal Circuit. By a decision dated November 23, 1993, the Federal Circuit affirmed Judge Robinson's decision stating that "the Claims Court properly determined that the Chief Special Master did not misapply the burden of proof." (App. at 51).

As the Special Master's requirement of actual causation is inconsistent with the plain language of the Vaccine Act which requires only that the petitioner show that a vaccine was more likely than not the cause of her injuries, she filed this petition for a writ of certiorari.

REASONS FOR GRANTING THE WRIT

Supreme Court review of this case is warranted because it involves an issue of first impression to the Supreme Court involving the misinterpretation of a major federal statute which will have a severe negative impact on thousands of pending claims for vaccine compensation and because the lower Court's decision is in conflict with a recent Supreme Court decision.

This case calls into question the proper burden of proof to be applied to a petitioner's claim for compensation under the Vaccine Act. The Vaccine Act is a major piece of federal legislation that Congress enacted to address what it called "the Nation's top public health priorities." H.R. Rep. No. 908, 99th Cong., 1st Sess., (1986) reprinted in 1986 U.S.C.C.A.N. 6344, 6345 (emphasis added). With the interpretation of such important federal legislation at

stake, Supreme Court review is warranted. United States v. Donovan, 429 U.S. 413, 422 (1977)(granting certiorari where issues "concern the construction of a major federal statute").

This case will also have a significant impact upon thousands of vaccine compensation claims pending before the U.S. Court of Federal Claims.[3] If allowed to stand, the

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[3]Just one week before the Federal Circuit's decision in this case, the Federal Circuit issued a decision denying a petitioner's claim for compensation, stating that the petitioner had not shown that the vaccine caused the petitioner's injuries. Hodges v. Secretary of the Dep't of Health & Human Servs., 9 F.3d 958 (Fed. Cir. 1993). The facts, however, do not support the Court's conclusions. Kara Hodges was born on December 2, 1982; a healthy baby. On February 23, 1983 at around 2:45 p.m. she received her first DPT shot. Kara had two screaming and crying episodes that afternoon. After the second, Kara's mother put Kara in her crib to cry herself to sleep. Within 30-45 minutes, Kara's mother checked on her and found that Kara was limp, pale, unresponsive and not breathing. Kara was taken to the hospital but could not be revived and was pronounced

(continued...)

Federal Circuit's interpretation of The Vaccine Act could result in the denial of hundreds if not thousands of these pending claims. In light of the incredibly large number of claims that are presently and potentially affected by this ruling, Supreme Court review is warranted. See Laing v. United States, 423 U.S. 161, 167

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[3](...continued)
dead at 6:31 p.m. The diagnosis was sudden infant death syndrome (SIDS). Id. at 953.

In her claim for vaccine compensation, Kara put forth the testimony of two physicians who stated that Kara's death was more likely than not the result of her vaccinations. The Special Master denied her claim for compensation stating that "[proof that] the DPT vaccine may cause death is not proof that it did in a particular case." Hodges v. Secretary of Dep't of Health & Human Servs., 9 F.3d 958 (Fed. Cir. 1993). The Federal Circuit's decision to affirm the Special Master in this case is particularly disturbing as there was absolutely no evidence of any other cause of Kara's death. The dissent, in a thoughtful and thorough review of the standard of proof under the Vaccine Act criticized the majority for allowing the Special Master to hold the petitioner to a burden of scientific certainty instead of a mere preponderance of the evidence. Hodges, 9 F.3d at 962.

(1976)(granting certiorari to resolve an issue pending in seventy federal cases).

The Federal Circuit's decision is also not in accordance with the law because it conflicts with a recent decision of the Supreme Court. In Daubert v. Merrell Dow Pharmaceutical, Inc., 125 L.Ed.2d 469, (1993), the Supreme Court held that "'general acceptance' is not a necessary precondition to the admissibility of scientific evidence." However, the standard relied upon to deny Petitioner's claim for compensation was set forth by the U.S. Court of Appeals for the Federal Circuit in Grant v Secretary of Dep't of Health & Human Servs., 956 F.2d 1144 (Fed. Cir. 1992). In Grant, the Federal Circuit stated that in order for a petitioner to prevail on a claim for vaccine compensation the petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation-in-fact requires proof of a logical sequence of cause and effect showing the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted). As interpreted by the Special Master and the U.S. Claims Court and implicitly affirmed by the U.S. Court of Appeals for the Federal Circuit, this standard contravenes the intent of Daubert by requiring Petitioner's medical testimony to be supported by peer-reviewed medical literature and epidemiological studies. In light of the conflict between the Supreme Court and the U.S. Court of Appeals for the Federal Circuit, Supreme Court review is warranted. United States v. Doe, 465 U.S. 605, 610 (1984).

To prevail on a claim for vaccine compensation, the Vaccine Act requires a petitioner to prove by a preponderance of

the evidence that a vaccine was the cause of her injuries. 42 U.S.C. § 300aa-13(1)(B). Even in cases such as this one, involving an off-Table injury,[4] the intent of Congress was to compensate individuals who could demonstrate through scientific studies or expert medical testimony that their injuries were vaccine-related. Congress specifically

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[4]The Vaccine Act established two alternative methods of recovery. The primary method of recovery under the Act simply requires the Petitioner to show that the injury manifested itself within the time frame set forth in an Injury Table (hereinafter "Table") set forth in the Act. 42 U.S.C. § 300aa-11(c)(1)(C)(i). If these requirements are met a presumption of causation applies. Id. Claims within this group are known as "Table" injuries. If the requirements of the Table are not met either because the time frames are not met or the Petitioner's particular reaction is not listed in the Table, the presumption of causation does not apply and the Petitioner is required to prove causation by a preponderance of the evidence just as she would be required to do in traditional tort litigation. 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Claims that fall under this category are known as "off-Table" injuries.

addressed the issue of the proper burden of proof with regard to off-Table injuries, stating:

> evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for [off-Table injuries] . . . The Committee does not intend, however, to susgest (sic) that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed to be eligible for compensation without further showings of causation.

H.R. Rep. No. 908, 99th Cong., 1st Sess., (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6356. Thus, Congress clearly intended to compensate individuals who could demonstrate through medical testimony that a vaccine was more likely than not the cause of their injuries. Congress clearly did not intend to require proof to a scientific certainty with regard to off-Table injuries. To require petitioners, as the Special Master did in this case, to prove that a vaccine "actually" caused the petitioner's injury

goes far beyond the requirements of the statute.[5] The Special Master improperly held the Petitioner to a stricter, virtually unattainable, standard in this case and his decision, therefore, is not in accordance with the law.

The Special Master's misinterpretation of the statutory burden of proof was affirmed by Judge Robinson of the U.S. Court of Claims who stated that:

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[5]What is even more remarkable about the Federal Circuit's requirement of actual causation is that this standard of proof is even higher than the standard of proof required in traditional tort litigation. In an analogous case, prior to the enactment of the Vaccine Act, the Ninth Circuit affirmed a 1.1 million dollar jury verdict against the manufacturer of the DPT vaccine brought by a man who was stricken with transverse myelitis after receiving a DPT vaccination. Toner v. Lederle Labs., 828 F.2d 510 (9th Cir. 1987), cert. denied, 485 U.S. 942 (1988). Neither the trial court nor the appellate courts were persuaded by the defendant's claim that the plaintiff could not show that his injuries were actually caused by the vaccine. Id.

> Chief Special Master Golkiewicz found that petitioner was unable to demonstrate that the vaccinations caused Heather's transverse myelitis. Once he found that petitioner failed to meet her burden of proof, the Chief Special Master did not need to, and did not, determine what did cause the disease in this case. This result is not surprising given that physicians have yet to solve the mystery of what causes transverse myelitis in infants. The court will not attempt to solve the mystery either.

(App. 43)(emphasis added). It is important to recognize that Judge Robinson did not find that the Special Master found the weight of the evidence to be against the Petitioner. Judge Robinson specifically found that the Special Master denied Petitioner's claim on the basis that she failed to meet her burden of proof with regard to the actual cause of the Petitioner's injury. The Special Master denied the Petitioner's claim, in effect, because medical science could not provide a definitive answer regarding the question of

causation.[6] This is not the standard that is set forth in the Vaccine Act. The Vaccine Act simply requires the Petitioner to prove by a preponderance of the evidence that her injury was caused by a vaccine. 42 U.S.C. 300aa-13(a)(1) and 300aa-11(c)(1)(C)(ii)(II).

The Federal Circuit's adoption of an actual causation standard completely frustrates the purpose of the Vaccine Act which was to make it easier, not harder, for individuals to recover from vaccine related injuries. The Vaccine Act was enacted by Congress in 1986 in response to a growing concern among state and federal officials regarding the "inadequacy-from both the perspective of vaccine-injured persons as

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[6]A thoughtful and thorough discussion of the difference between scientific and legal causation in the context of The Vaccine Act is set forth in Judge Newman's dissent in Hodges, 9 F.3d at 962.

well as vaccine manufacturers- of the current approach to compensating those who have been damaged by a vaccine." H.R. Rep. No. 908, 99th Cong., 1st Sess., reprinted in 1986 U.S.C.C.A.N. 6344, 6346. By enacting this legislation, Congress hoped "to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries." Id.

This great purpose has been gutted from the Act by the Federal Circuit's adoption of an actual causation standard. As a result of applying this strict standard, a substantial number of children who have been injured by vaccines will be left uncompensated. This result is clearly at odds with the stated intent of Congress which was to compensate

even those individuals who, at the time, had no legal remedy under common law.[7]

CONCLUSION

The United States Court of Appeals for the Federal Circuit adopted an interpretation of the Vaccine Act that will result in the denial of hundreds if not thousands of claims for compensation based upon the inaccurate statutory interpretation that these children are required to prove that a vaccine actually caused their injuries. This interpretation directly contravenes the plain language of the statute which requires an injured child to show that her injury was

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[7]The House Report states that the members of the committee "recognize[d] that because of many States' standards of proof of liability, many vaccine-injured persons are presently without legal remedy under current tort law. The Committee anticipates that many of these persons will be compensated for their injuries under the compensation system." H.R. Rep. No. 908, 99th Cong., 1st Sess., reprinted in 1986 U.S.C.C.A.N. 6344, 6354 (emphasis added).

more likely than not a result of a vaccine. If left unchallenged, this interpretation will completely frustrate the stated purpose of the Act and will once again place the burden of the country's vaccine efforts upon the shoulders of innocent, unsuspecting children. For these reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

KOONZ, MCKENNEY, JOHNSON
& REGAN, P.C.

BY: _____

Keith W. Donahoe
2020 K Street, N.W.
Suite 840
Washington, D.C. 20006
(202) 659-5500

Attorney for Petitioner

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No. 90-903V
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Linda L. McCummings,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Keith W. Donahoe, Washington, D.C., for petitioner.
Caroline F. Goss, Washington, D.C., for respondent.

ENTITLEMENT DECISION[1]

Golkiewicz, Chief Special Master

On behalf of her minor daughter, Heather Renee McCummings, petitioner filed for compensation under the National Vaccine Injury Act of 1986 (the "Vaccine Act" or the "Act"). Petitioner claims that as a direct result[2] of the administration of a diphtheria, pertussis, tetanus (DPT) and oral polio vaccinations (OPV) on February 16, 1981, Heather suffered trans-

[1]The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§ 300aa-1 - *et seq.* (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

[2]Since the onset of Heather's injuries occurred five days post vaccination, petitioner received no benefit from the Act's statutory presumption of causation, but had to prove that the vaccine in-fact caused Heather's injuries.

verse myelitis.[3] In the petition filed on September 10, 1990, petitioner initially alleged that Heather's transverse myelitis was a result of a DPT vaccination. Pet. Ex. A at 1. On January 31, 1991, petitioner amended her petition to allege that Heather's injury was a result of both the DPT and OPV vaccinations. Amended Pet. at 1-2.

Respondent filed a report (HHS Report) on May 31, 1991, recommending that petitioner's claim be denied and her case be dismissed. An evidentiary hearing was held on April 16, 1992, in Washington, D.C., at which petitioner and her medical expert, Dr. Shlomo Shinnar testified. Respondent presented the testimony of Dr. William Robertson. Pursuant to § 12(d)(3)(A) and Vaccine Rule 10(a) and for the reasons stated below, the undersigned finds that petitioner is not entitled to compensation under the Vaccine Act.

FACTUAL BACKGROUND[4]

Heather was born on July 21, 1980, a term product of an uncomplicated pregnancy delivered via Cesarean section for floating frank breech presentation. Pet. Ex. B(1) at 5. At birth, Heather's APGAR[5] scores were nine and ten, with no congenital anomalies present. Pet. Ex. B(3) at 11, 13. On Au-

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[3]Transverse myelitis is defined as a myelopathy which extends across the spinal cord. *Dorland's Illustrated Medical Dictionary* 1088 (27th ed. 1988).

[4]The evidence in the record in this case consists primarily of exhibits submitted as part of the petition filed in the case ("Pet. Ex. ____"), respondent's exhibits filed in this matter ("Res. Ex. ____"), as well as testimony taken at the April 16, 1992 hearing ("Tr. at ____").

[5]A numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex irritability, and color. *Dorland's Illustrated Medical Dictionary* 1498 (27th ed. 1988).

gust 4, 1980, Heather received her first pediatric visit, at which time it was noted that Heather was doing well. From August 8, 1980 to December 8, 1980, Heather was examined by her pediatrician approximately once a month.[6] On September 23, 1980, Heather received her first DPT and OPV vaccinations apparently without ill effects. Pet. Ex. B(2) at 7-8, Tr. at 13. On February 16, 1981, Heather received her second DPT and OPV vaccinations administered by Dr. Rostogie. Dr. Rostogie noted at that visit that Heather was "doing well." Pet. Ex. B(2) at 8.

Mrs. McCummings testified, and the medical records corroborated, that five days following the administration of the vaccinations on February 16, 1981, petitioner observed that Heather was unable to move her legs or sit up. Pet. Ex. B(4) at 23, 24; Ex. B(5) at 30, 32, 34.[7] On February 23, 1981, following an examination by Dr. Rostogie,[8] Heather was admitted to Hartford Memorial Hospital with a diagnosis of probable transverse myelitis. Pet. Ex. B(3) at 15. A neurological examination conducted by Dr. Douglas Abbott on February 23, 1981, revealed ". . . spastic para-paresis present in the lower extremities, with sustained clonus at the ankles". Pet. Ex. B(4) at 23. Dr. Abbott's impression was that Heather was suffering from either transverse myelitis secondary to the vaccinations or a spinal cord tumor. *Id.* Upon his recommendation, Heather was transferred later that same day to the

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[6]Except for an upper respiratory infection on December 8, 1980, Heather appeared to be a well baby.

[7]Although the medical records documented this history, at the hearing petitioner testified that although she noticed Heather having difficulty moving her legs on February 21, 1981, petitioner could not recall attempting to place Heather in a sitting position. Tr. at 25.

[8]Dr. Rostogie documented the following note during this visit "T-98.6 normal. Mother states patient is not moving both the lower extremities for two days. Slightly fussy, no fever." Pet. Ex. B(2) at 9.

University of Maryland Hospital for further diagnostic evaluation.

During the eight day hospitalization, Heather received an extensive diagnostic work-up,[9] including an infectious disease consult by Dr. Margaret Rennels, and a pediatric immunologic consultation by Dr. Huany. Physical exam on admission to the University of Maryland Hospital revealed flaccid paralysis of Heather's lower extremities, decreased rectal tone, and dribbling of urine with suprapubic pressure. Pet. Ex. B(5) at 32-34. Dr. Rennels evaluated Heather on February 24, 1981. Dr. Rennels documented a history taken from the mother, that Heather exhibited a slight runny nose and temperature of 100 degrees Fahrenheit on February 21, 1981. Dr. Rennels's assessment included a discussion of Heather's recent receipt of the DPT and OPV vaccinations five days prior to the onset of symptoms. Although Dr. Rennels doubted that Heather's symptoms were evidence of polio, she documented that she would discuss Heather's symptomatology with several polio experts. Dr. Rennels's also stated "[o]ther possibilities include Guillain-Barre[10] and transverse myelitis which are associated with a number of infections." Pet. Ex. B(5) at 33. Dr. Rennels recommended serologic testing for various viruses, and an immunologic work-up. Heather was also examined by Dr. Gumbinas on February 24, 1981. Dr. Gumbinas stated "[t]ransverse myelitis already improving temporally related to DPT and OPV vaccine. Rule out viral infection with polio, coxsackie, echo." Pet. Ex. B(5) at 34-35.

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[9]Heather received a myelogram, lumbar puncture, skull and hip X-rays, and an EMG, which were all normal. Serologic titers performed on February 25, 1981 and April 13, 1981, revealed only a rise in Polio III form 1:4 to 1;32. Heather's urine and cerebrospinal fluid cultures were negative.

[10]Guillain-Barre syndrome is an acute febrile polyneuritis which is an inflammation of many nerves at the same time. *Dorland's Illustrated Medical Dictionary* 722 (27th ed. 1988).

The medical records also contained a consultation dated February 26, 1981, by pediatric immunologist Dr. Huang. Pet. Ex. B(5) at 37. Dr. Huang discussed the temporal relationship between the administration of Heather's vaccinations and the onset of the paralysis. Dr. Huang documented a study of 3000 cases in which participants received a DPT or DT vaccination which resulted in several episodes of seizures or some other type of central nervous system involvement. No cases of paralysis were reported. Although several immunocompromised hosts developed polio following the vaccination, most cases had compound immunological deficit. Dr. Huang noted "[w]e however saw one who had selective IgA deficiencies who developed paralysis." *Id.* at 37. For this reason, Dr. Huang recommended serum IgM, IgA, and IgG measurements.[11]

At the time of discharge, Heather's leg movements, as well as urinary problems, had improved considerably. Pet. Ex. B(4) at 43. However, as a result of the transverse myelitis, Heather continued to experience orthopedic, as well as urinary problems.[12] Heather is currently in the fourth grade. Heather is ambulatory for short distances. She has decreased movement of the right foot and ankle, and uses a brace for her right leg at night. Heather also performs urinary self-catheterization every four hours due to the neurogenic bladder. Heather receives her follow-up care at the Alfred I. DuPont Institute, the Nemours Foundation, in Wilmington, Delaware. Pet. Ex. B(10) at 176.

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[11]Heather's immunological work-up was subsequently negative. P. Ex. B(5) at 48.

[12]On December 5, 1983, Heather underwent surgery for bilateral lengthening of the tendo Achillis. Heather also was diagnosed with a neurogenic bladder for which she underwent a sigmoid augmentation bladder procedure. Pet. Ex. B(10) at 102; Pet. Ex. B(12) at 259. This is a procedure in which the bladder is enlarged by grafting to the bladder a detached segment of intestine. *Dorland's Illustrated Medical Dictionary* 425 (27th ed. 1988).

Expert Testimony

Petitioner presented the testimony of Dr. Shlomo Shinnar,[13] a board certified neurologist with special competence in child neurology and pediatrics. Tr. at 27. Dr. Shinnar testified that he agreed with the diagnosis of transverse myelitis and opined that Heather's transverse myelitis was related to the immunizations administered five days prior to the onset of her symptoms. Tr. at 14. Dr. Shinnar posited two theories regarding the cause of Heather's transverse myelitis. Firstly, Dr. Shinnar testified that transverse myelitis can occur either as a result of an acute viral syndrome or as a hyper-immune response to a variety of agents. Tr. at 34. The most common viruses implicated with the acute viral syndrome are the Epstein-Barr virus, influenza virus, and mononucleosis virus. Tr. at 34. Dr. Shinnar explained that a hyper-immune response can occur as a result of a variety of agents. The agent can be either a prior viral infection or any antigen which causes the body to act in an abnormal fashion, *i.e.*, the body begins to attack its own tissue in response to what the body perceives is a foreign substance. Tr. at 34. This hyper-immune response has been implicated with several types of immunizations, notably smallpox. *Id.* Secondly, he testified that Heather's transverse myelitis was the result of a vaccine induced hyper-immune response.

Dr. Shinnar ruled out the possibility of an acute viral syndrome as the cause Heather's transverse myelitis. Dr. Shinnar

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[13]Dr. Shinnar obtained his M.D. and Ph.D degrees in neurophysiology from Albert Einstein College in 1978. Dr. Shinnar completed a pediatric and neurology residency and fellowship at Johns Hopkins Hospital from 1978-1983. He is currently an associate professor of neurology and pediatrics, as well as chief of the pediatric neurology clinic at the Montofuie Medical Center of the Albert Einstein College of Medicine in New York. Tr. at 27.

bases his conclusion on the absence of clinical findings of a viral infection. Dr. Shinnar noted that Dr. Rennels, the infectious diseases specialist, who examined Heather on February 24, 1981, made no documentation on physical examination of an acute infection, although Dr. Rennel's history mentioned a previous history of a slight runny nose. Pet. Ex. B(5) at 32; Tr. at 37. Although one of the medical records documented a history of a runny nose[14] on February 21, 1981, the physical findings under HEENT states "nose-no discharge". Pet. Ex. B(5) at 28. Even if the runny nose began two days prior to the onset of symptoms, Dr. Shinnar testified that if an acute viral process was the cause of Heather's transverse myelitis, the runny nose should have begun a week or so prior to the onset of symptoms. Tr. at 67.

Dr. Shinnar also discounted an acute viral syndrome as the cause of Heather's transverse myelitis based on the absence of white cells in Heather's cerebro-spinal fluid. Dr. Shinnar testified that during an acute viral infection, one would see 50, 60, or 70 white blood cells in the cerebro-spinal fluid which would be evidence of an inflammatory process. Tr. at 108. The absence of white cells in Heather's cerebro-spinal fluid[15] argued against an acute viral invasion and made it more likely an immune medicated response, whether it was a virus or immunization. *Id.*

Dr. Shinnar discounted the possibility that Heather's transverse myelitis was caused by a post viral hyper-immune response. He explained that if a post-viral hyper-immune re-

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[14]One medical record documents that Heather exhibited a runny nose beginning the morning of February 23, 1981. P. Ex. B(5) at 26. A second medical record dated February 24, 1981, documents a history of a runny nose on February 21, 1981. P. Ex. B(5) at 32.

[15]Heather's cerebro-spinal fluid contained four white blood cells. Pet. Ex. B(5) at 33.

sponse was the cause of Heather's transverse myelitis, one would expect to see signs of infection two to three weeks prior to the onset of the symptoms. Heather's only history of a viral illness was six weeks prior to the hospital admission, which Dr. Shinnar testified is outside the two to three week time frame necessary for a virally induced hyper-immune response. Tr. at 39. Secondly, Dr. Shinnar discounted a viral syndrome as the cause of Heather's transverse myelitis based on the absence of a rise in viral titers drawn on April 13, 1981. Dr. Shinnar testified that normally if a virus triggers an immune response, then a rise in viral titers will be evident two months after the initial set was obtained, assuming the causative virus was tested for. Tr. at 43. Heather's titers for the coxsackie virus, echo virus, mononucleosis virus, and Epstein-Barr virus, as well as several others, were initially drawn on February 25, 1981. These viruses remained unchanged on April 13, 1981. Pet. Ex. B(5) at 47; Tr. at 43. Heather exhibited a rise in the polio titers[16] which Dr. Shinnar stated was merely evidence that the polio vaccine administered on February 16, 1981, was effective. Heather was tested for the most common viruses and no rise was documented. Since there was no evidence by clinical findings on serologic testing, Dr. Shinnar stated that on a "more likely than not basis" the vaccines caused Heather's transverse myelitis. Tr. at 96.

Dr. Shinnar's opinion that Heather's transverse myelitis was caused by a vaccine induced hyper-immune response was based on deductive reasoning. He recognized transverse myelitis as a rare entity in Heather's age group. He also recognized that although the medical literature lists two vacci-

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[16]On February 25, 1981, the serology titer for polio type I was 1:64; on April 13, 1981, the titer was 1:152. The titer for polio type 3 on February 25, 1981 was 1:4; on April 13, 1981 the titer was 1:32. Pet. Ex. B(5) at 47.

nations, rabies and smallpox, as being associated with transverse myelitis, DPT and OPV are not listed as potential causative agents of transverse myelitis. However, Dr. Shinnar parts company with the literature arguing that in theory there is no reason to believe the list of viruses and vaccinations to be exhaustive. Thus, he stated that:

> [f]rom the immunological point of view, we can certainly argue that one type of vaccine, or virus, or bacteria is more likely to cause a set of symptoms. But from all we know about hyper-immune reactions such as Guillain-Barre, transverse myelitis, or any other, it is not that specific. And if you can accept that it can occur from immunization, then it can occur from immunization. It may be less common with DPT than with smallpox immunization. But the notion that it can occur with this immunization and not another would require a set of hypothesis that are simply not supported by the medical literature, all of which said that it is more likely with this type but it can occur with others.

Tr. at 48.

When asked whether the vaccinations are in any way different, to explain why some are recognized in association with transverse myelitis and others are not, Dr. Shinnar stated that "certain types of reactions are more common with certain types of both vaccine and illness." Tr. at 52. However, while recognizing that some viruses and vaccinations are seen more commonly as causative agents, Dr. Shinnar averred that:

> [n]obody has ever argued that other viruses cannot produce it as a post-reaction and I would say that the same arguments goes for all hyper-immune responses. Once you accept the notion that this

> kind can produce it, others may be less likely to, but they ought to.

Tr. at 53.

Upon questioning by the court, Dr. Shinnar agreed that it made no sense to him to recognize that transverse myelitis can occur from the rabies vaccine but not from the DPT vaccine. Dr. Shinnar opined that if you accept the mechanism of one or two immunizations causing transverse myelitis, you should accept it for all, not withstanding that the frequency of occurrence may be different. Tr. at 73. However, Dr. Shinnar stated that:

> [y]ou would have expected to see evidence of an infection a few weeks earlier or in fact a week earlier. And what she got the week earlier was the vaccine, not evidence of a clinical infection.

Tr. at 40.

Although Dr. Shinnar argued that normally, a post-viral hyper-immune response will exhibit signs of infection one to two weeks prior to the onset of symptoms, he admitted that not all viruses have noticeable symptoms. According to Dr. Shinnar, infants frequently display more subtle signs of a viral process *i.e.*,a sub-clinical virus. *Id.* at 79. Thus, he conceded the possibility that the virus could be asymptomatic, *i.e.*, without symptoms. *Id.* at 92. In fact, Dr. Shinnar admitted that on a theoretical basis, it was possible that an asymptomatic virus was the cause of Heather's transverse myelitis, and stated that if Heather had not received a vaccine in this case, "maybe she had a sub-clinical viral infection". Tr. at 41, 90.

In response to the court's questioning why an asymptomatic virus should not be seen as the likely causative agent in this case, Dr. Shinnar stated that while it was a possibility, he found

it less likely. First, analyzing Guillain-Barre Syndrome,[17] Dr. Shinnar explained that in at least 50% of Guillain-Barre cases there is definite evidence of an antecedent viral infection. He also stated that if patients are suffering from an acute viral infection but are asymptomatic, the virus can be cultured. In Heather's case, the serology titers drawn for the most common viruses implicated in a post-viral hyper-immune response, admittedly not an exclusive list, were negative. Therefore, he explained that if the cultures are negative and the titers for the most common viruses implicated with a post-viral auto-immune response are negative, then the diagnosis, without any other intervening temporal event, would ***probably be an asymptomatic viral infection***. However, in Heather's case, Dr. Shinnar stated because there is a known temporal association between the vaccinations and onset of symptoms, and no evidence of a viral syndrome, then this becomes a judgment matter of "more likely than not." Tr. at 91. According to Dr. Shinnar:

> What I'm saying is that on a theoretical basis both are possible. But we have a known vaccine five days ago, we haven't any conclusive evidence of a vaccine [sic] either by symptoms of by serological testing or by anything else and therefore on a more likely that not basis, it was the vaccine. That's all I'm saying. I'm not trying to make it — I cannot make it stronger than that and that's the evidence.

Tr. at 96.

[17]Dr. Shinnar referred to Guillain-Barre Syndrome based on the fact that the same viruses have been implicated in both disease processes, and testified that Guillain Barre and transverse myelitis are believed to be the same type of mechanism. Tr. at 35, 88. The Respondent's expert, Dr. Robertson, testified that transverse myelitis is an entirely different clinical entity than Guillain-Barre syndrome, and any association between the DPT vaccine and Guillain-Barre is extremely tenuous. Tr. at 182.

Dr. Shinnar stated that it becomes a probability argument in deciding which of the two possibilities were the cause of Heather's injuries, the immunization or an asymptomatic viral illness. Tr. at 95, 106. Dr. Shinnar discounted the viral theory since "fifty percent of the time or less will you be asymptomatic. Of those, in a large chunk of them, you ought to find the titers". Tr. at 95. However, in response to the court's question whether it was reasonable for Heather's parents not to notice symptoms until Saturday, February 21, 1981, Dr. Shinnar stated it was reasonable and expected, whether the transverse myelitis was caused by a vaccine or virus. Tr. at 138. Thus, Dr. Shinnar stated:

> If you had nothing else because there was no immunization and you have a kid with a transverse myelitis, you're going to end up after you do a work-up for other things and you don't find anything, saying well, I guess most likely it's post-viral because we know there's an association.

Tr. at 107.

As support for his theory that the vaccinations caused Heather's transverse myelitis, Dr. Shinnar relied on a scientific article describing three different case studies involving the article describing three different case studies involving the administrations of diphtheria, tetanus, and oral polio vaccines and the development of transverse myelitis.[18] The Whittle article involved a case study of a seven-month old female diagnosed with transverse myelitis, who experienced lower extremity paralysis and fever six days subsequent to receiving both DT and OPV vaccinations. The article described the physical findings, laboratory results, and hospital course of the patient. The authors first noted that the onset of symptoms occurred at

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[18]E. Whittle, *Transverse Myelitis after Diphtheria, Tetanus, and Polio Immunisation*, British Medical Journal 1:1450 Vol. 1, June 4, 1977 (hereinafter Whittle).

the same time other reactions to immunizations are frequently found. The authors distinguished two reported cases involving patients who developed transverse myelitis following the administration of an oral polio vaccine and diphtheria vaccine respectively. The former case study involved an infant with transverse myelitis following the oral polio vaccine whose course was complicated by cytomegalovirus infection. The latter case study involved a 22-year-old male who developed transverse myelitis following a diphtheria vaccine. This study, therefore, was the first to report transverse myelitis in association with the use of ***either*** oral polio or diphtheria and tetanus vaccinations in an otherwise healthy infant. The authors concluded, in the absence of other evidence, they could not be sure which of the antigens was most likely responsible for the myelitis.

Dr. Shinnar stated that Heather's course of illness was very similar to the case study involving the seven month old infant. Dr. Shinnar also stated that since transverse myelitis is such a rare entity in this age group, the temporal relationship of these two events occurring carries more weight than two events, temporally related, which are relatively common. Tr. at 47.

Dr. William Robertson,[19] board certified in neurology and pediatrics, testified for the respondent. Dr. Robertson opined to a reasonable degree of medical certainty that Heather's transverse myelitis was not causally related to the polio and DPT immunizations. Tr. at 147. Dr. Robertson testified that Heather's transverse myelitis was caused by a viral infec-

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[19]Dr. Robertson received his medical degree from Emory University in 1967. He completed his internship at John Hopkins Hospital, and spent two years as a general medical officer at the Naval Hospital in Portsmouth. Dr. Robertson served as Chief of Pediatrics at the Naval Hospital at Camp LeJeune, followed by a three year fellowship in child neurology at the Mayo Clinic. He was an assistant professor of Neurology and Pediatrics at the University of Wisconsin for two years. Dr. Robertson is currently an associate clinical professor of Neurology at the University of Kentucky and has been with the Lexington Clinic for twelve years. Tr. at 144-145.

tion.[20] Dr. Robertson based his conclusion on evidence in the clinical record that Heather's secondary discharge diagnosis was an upper respiratory tract infection. Pet. Ex. B(6) at 45; Tr. at 148. Dr. Robertson was of the opinion because the diagnosis of transverse myelitis was accurate, he assumed this secondary diagnosis was also correct. Dr. Robertson also stated that Dr. Rennel's note dated February 24, 1981, documented a history of temperature of 100 degrees Fahrenheit on February 21, 1981, which is compatible with a mild viral infection. Pet. Ex. B(5) at 32; Tr. at 149. Dr. Robertson also noted that Heather's physical examination revealed clear lung fields which supported the finding of an upper respiratory infection. Dr. Robertson also relied upon the consultation note of Dr. John Freeman, who performed a neurologic examination of Heather on October 29, 1981. Dr. Freeman's impression was that any relationship between the immunizations and transverse myelitis was highly unlikely. Pet. Ex. B(8) at 68.

Dr. Robertson testified that the available literature has consistently proposed an association between transverse myelitis and a preceding or concomitant viral infection. Tr. at 156. He also stated that a viral infection can occur at the time a transverse myelitis is developing, so the absence of a previous viral infection does not exclude an association between Heather's upper respiratory infection to the development of the transverse myelitis. Tr. at 157. Dr. Robertson testified that a severe viral infection is not necessary for the development of transverse myelitis. The fact that Heather exhibited only mild symptoms, *i.e.*, a low grade fever and runny nose, did not rule out the fact that a virus caused Heather's transverse myelitis. Tr. at 160.

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[20]Dr. Robertson testified that he did not believe the literature distinguished between acute and post viral infections. Tr. at 158.

Dr. Robertson was not of the opinion that the Whittle article supported a cause and effect relationship between immunizations and the development of transverse myelitis. Tr. at 150. Dr. Robertson thought that the article contained some suggestion that the seven month old infant may have had a preceding or concurrent viral infection as her transverse myelitis developed, thus supporting the existing literature.[21] Tr. at 151. He also noted that the authors did not conclude definitively that the child's transverse myelitis was caused by the immunizations, but rather only proposed an association. Tr. at 151.

Dr. Robertson admitted on cross-examination that the literature suggests either a viral etiology or auto-immune response theory for the development of transverse myelitis. Tr. at 161. Dr. Robertson admitted that there is no scientific evidence to support the theory that transverse myelitis is caused by a virus. However, because a viral infection is frequently mentioned in the literature with the development of transverse myelitis, and based on Heather's history of a low grade fever and runny nose, Dr. Robertson concluded that a virus was the cause of her transverse myelitis. Tr. at 175.

The Statutory Requirements

The Vaccine Act permits petitioners to establish causation in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. The Vaccine Injury Table lists specific vaccines and certain injuries or conditions that may occur as a result of a vaccine's administration. If the onset of those injuries or conditions is found

[21]The article states "[a] seven month old girl was admitted to hospital with a four day history of a slight cough and a hoarse cry associated with mild irritability and lassitude". Whittle at 1450.

to occur within the prescribed time frames, a rebuttable presumpton is created that the vaccine caused the condition. Evidentiary requirements have been relaxed for cases that fall within the Table, but no such relaxation of proof has been provided for off-Table injuries. *Strother v. Secretary of HHS*, 18 Cl.Ct. 816 (1989) *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991).

To prove causation in-fact, petitioners must affirmatively demonstrate by a preponderance of the evidence that the DPT vaccine caused Heather's transverse myelitis.[22] Thus, petitioner's case is more difficult to prove. Not only is the proof of injury necessary, but petitioner also bears the burden of linking the injury directly to the vaccine. The burden rests on the petitioner to show that the vaccination in question more likely than not caused the specific injury, under the same standards which apply in traditional tort litigation. *See Hines v. Secretary of HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). As the House Committee on Energy and Commerce stated, in commenting on the causation in fact under the Vaccine Act:

> [T]he petitioner must affirmatively demonstrate that the injury or aggravation was caused by the vaccine. Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner.

H.R. Rep. No. 908, 99th Cong., 2d Sess. 15 (1986), *reprinted in* 1988 U.S. Code & Admin. News 6344, 6356. Petitioner does not meet this affirmative obligation by showing merely a temporal association with the vaccination, *see Hasler v. United States*,718 F.2d 202, 205 (6th Cir. 1983), *cert. denied*,

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[22] § 11(c)(1)(C)(ii)(I).

469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it); nor by eliminating other potential causes of the injury. *See Grant v. Secretary of HHS*, 956 F.2d 1144, 1149, (Fed. Cir. 1992). In *Grant*, the Federal Circuit summarized the legal criteria required to prove causation-in-fact under the Vaccine Act. The court noted that a petitioner must:

> Show a medical theory causally connecting the vaccination and the injury. Causation-in-fact requires proof of a logical sequence of cause and effect showing the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant 956 F.2d at 1148 (citations ommitted); *see also, Strother v. Secretary of HHS*, 18 Cl. Ct. 816 (1989), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991).

In this case, the facts are uncontroverted. The only issue is the cause of Heather's transverse myelitis. Although the actual etiology of transverse myelitis is unknown, the current medical literature suggests two alternate theories which have been proffered by both medical experts. However, as recognized by Dr. Robertson, while viruses and certain immunizations are frequently mentioned as being "associated" with transverse myelitis, there is no hard evidence or scientific proof to support such a linkage. Tr. at 169-71. Thus, Dr. Robertson agreed with the court that his theory that transverse myelitis is virally induced is subject to essentially the same criticism as petitioner's theory of a vaccine induced cause of transverse myelitis, mainly lack of medical support. *Id.* at 171. The major difference, of course, is that petitioner bears the burden of proof.

This is a case of first impression with the court. According to

the medical experts who testified and based upon the medical literature submitted, while transverse myelitis is "associated" (defined by Dr. Robertson as "suggest[ing] chance," Tr. at 171) with certain causative agents, there are no epidemiological studies or other hard medical evidence to prove or disprove the cause of transverse myelitis in children. For guidance on how to resolve this difficult medical issue in the absence of medical studies, the court looked for guidance from other jurisdictions.

In causation cases, courts have rejected expert testimony, unsupported by a sound scientific theory, that contradicts published epidemiological studies relied upon by experts in that particular field. In *Ealy v. Richardson-Merrell, Inc.*,[23] the court held that in light of the published epidemiological data, an expert's opinion that Bendectin is a human teratogen[24] lacked scientific foundation in light of the published data to the contrary. This case arose from a products liability action in which the plaintiffs sought to recover damages from a child's birth defects allegedly caused by the mother's use of Bendectin. Plaintiffs' experts relied upon unpublished reinterpretations of the epidemiological literature, as well as *in vitro* and *in vivo* studies, as sufficient foundation to support their opinions that Bendectin was a human teratogen.[25] The court, noting this was the same theory of proof used and rejected in *Richardson v. Richardson-Merrell, Inc.*[26] held the experts' opinions inadmissible. According to the *Ealy* court, "[t]he body of published epidemiological opinions on the subject at hand is extensive, indeed massive, and all such opinions point to the same conclusion." *Ealy* at 140.

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[23]283 U.S. App. 137 (D.C. Cir. 1990).

[24]"An agent or factor that causes the production of physical defects in the developing embryo." *Dorland's Illustrated Medical Dictionary* 27th ed. at 1672 (1988).

[25]283 U.S. App. at 138.

[26]857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S.Ct. 218 (1989).

The *Richardson* court recognized that the causation issue before them was not based on novel scientific technique, but had been extensively researched resulting in a wealth of published epidemiological data, none of which concluded that Bendectin was teratogenic. The court refused to allow the plaintiff's expert testimony, and stated that "uniquely to this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their due." *Id.* at 832. The *Richardson* court was highly persuaded by the amount of published epidemiological studies all pointing to an absence of a causal link between the use of Bendectin and birth defects, and was comfortable in not admitting contrary expert opinion.

However, in *Ferebee v. Chevron Chemical*[27] the court was faced with a novel causation issue regarding whether paraquat, a known toxic agricultural herbicide, could cause pulmonary fibrosis. In *Ferebee*, a manufacturer of paraquat was sued by the estate of an employee who died from pulmonary fibrosis, which, they alleged he had contracted as a result of long term skin exposure to the paraquat in the workplace. The U.S. District Court for the District of Columbia's judgment on the wrongful death count for $60,000.00 against the manufacturer was affirmed by the Court of Appeals.

The decedent, Mr. Ferebee, began work in 1967 as an agricultural worker whose duties frequently involved spraying various chemicals, including insecticides and herbicides, on greenhouse plants. Mr. Ferebee began spraying paraquat in 1977, on the average six to seven times a month for a period of three years. Mr. Ferebee described frequent episodes of the spray on his skin, mainly his arms. He also described two episodes of more extensive exposure, one in which his head and arms became drenched with the spray resulting in dizzi-

[27]736 F.2d 1529 (1984), 237 U.S. App. 164.

ness and exhaustion, another in which a defective sprayer caused the substance to leak onto his pants, which he was unable to change until the end of the work day. *Id.* at 1532. In late 1977, Ferebee began to experience episodes of shortness of breath. His condition continued to decline, he was hospitalized in 1979, was diagnosed with pulmonary fibrosis and died on March 18, 1982.

His treating physicians, Drs. Yusef and Crystal, both testified that in their opinion the paraquat caused the pulmonary fibrosis. To support their opinions, the physicians relied upon their clinical examination, the medical tests conducted, and medical studies which suggested that dermal absorption of paraquat can lead to chronic lung abnormalities, such as pulmonary fibrosis. *Id.* at 1533. Defendants argued that first, the exposure to paraquat resulted in only acute toxicity, that when the exposure ceases, so does the injury. Second, defendants argued there had never been any evidence that paraquat caused chronic injuries of this type. Finally, defendants argued that the opinion testimony of Drs. Yusef and Crystal should be inadmissible because, while their views were not rejected by the medical community, they were too novel at this point. *Id.* at 1535.

The court noted that: 1) both doctors were eminent pulmonary specialists; 2) Dr. Crystal testified to three other clinical cases similar to Mr. Ferebee's; and 3) although both plaintiff's and defendant's experts relied on the same diagnostic methodology and reached contrary conclusions, the court addressed the fact that the opinions of the defendant's experts, who never treated or examined Mr. Ferebee, were not so substantial that the jury had no choice but to accept it. Thus, "[t]he case was a classic battle of the experts, a battle in which the jury must decide the victor."[28]

[28] *Id.* at 1535, *citing Jenkins v. United States*, 307 F.2d 637, 646 (D.C. Cir. 1962).

Regarding the admissibility of the expert's testimony, the court stated that legal sufficiency, ***not*** scientific certainty, should be weighed in allowing expert testimony to reach a jury. "If reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant." *Id.* at 1536. The Court also stated that:

> A cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.

Id. at 1535-1536.

In *Ferebee*, paraquat was an admittedly dangerous chemical. The court pointed out attempts to link low-level exposure to toxic chemicals with human disease raised complex causal issues, which are outside the competence of judges. "On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony." *Id.* at 1534.

It appears that this case falls squarely within the parameters set by the *Ferebee* court. **The experts in this case agree**

that there are no studies or hard evidence to assign a cause to transverse myelitis. Therefore, the court views this case as presenting a "novel" causation issue. The court will decide the case looking at the expert's reasoning, how the limited medical information supports that reasoning, and whether the reasoning is logically sound and in accordance with generally accepted medical practice.

Discussion

Petitioner's expert, Dr. Shinnar, bases his conclusion that Heather's transverse myelitis was caused by the vaccination on the absence of clinical findings of either an acute or post-viral infection, as well as on the theoretical possibility that immunizations other than those generally associated with transverse myelitis can be causative. While well presented, in the final analysis Dr. Shinnar's theory is just that, a theory, neither supported by medical evidence nor Dr. Shinnar's own testimony.

Both experts recognized transverse myelitis as a rare occurrence whose cause has not been definitely determined. While viruses are consistently documented in the literature as the most likely causative agent, there is no hard evidence to support the association. *See* Tr. at 170-71. While not agreeing with Dr. Shinnar, Dr. Robertson viewed Dr. Shinnar's theory, that if one vaccine can cause a hyper-immune response then any vaccine can cause a similar reaction, as not implausible:

> **I think that I cannot disagree with his theory. In other words, I recognize [that] his thinking is not illogical. He is proposing a theory, he is proposing a possibility. You know, there is no way that he can prove it and there is no way that I can disprove it.**

Tr. at 186.

As noted by the *Ferebee* court, in novel areas of medical questions, the requirements of evidence are changed from the preferred epidemiological studies to lesser circumstantial evidence that is generally relied upon by the profession. Dr. Shinnar recognized the slimness of support for his theory that the vaccinations were causative in this case. He stated that:

> [t]he only argument really exists on what is the evidence that this specific immunization has caused it. I would say that we have at least anecdotal reports, but the logic is if that's the mechanism there is no reason I can think of why it should not occur with this vaccine as well as we certainly have no convincing other evidence of an antecedent insult that might cause it.

Tr. at 61-62.

However, Dr. Shinnar's reasoning is built upon a house of cards. Dr. Shinnar relies upon anecdotal reports or other similar "associations", no proof that the DPT or polio vaccines cannot cause transverse myelitis, and no evidence of another cause, namely a virus. However, each of these three "cards" is either medically or legally deficient and, therefore, Dr. Shinnar's reasoning crashes accordingly.

Dr. Shinnar's "anecdotes" are in reality one — which occurred over fifteen years ago and which is highly dubious. Although initially Dr. Shinnar relied on all three case studies reported in the Whittle article as support for his theory that transverse myelitis can be caused by immunizations, he later agreed that two of the three case reports were complicated by intervening factors. Dr. Shinnar acknowledged that one case report involving an infant receiving a triple vaccine and develop-

ing transverse myelitis was complicated by the fact that the infant also had cytomegalovirus infection. Dr. Shinnar agreed that based on this case study, he was unable to conclude what particular antigen caused the transverse myelitis. He also acknowledged that the symptoms reported involving the seven month old infant documenting a four day history of a slight cough and irritability could be indicative of an upper respiratory infection. Tr at 116. Therefore, the only case report Dr. Shinnar admitted he could rely upon was that of the 22 year old male who developed transverse myelitis after receiving a diphtheria immunization.

The basic premise in the Whittle article, upon which Dr. Shinnar relies, is that the transverse myelitis occurred during the time frame one would expect to see reactions to immunizations. Since the transverse myelitis occurred within this time frame, absent other intervening causative agents, the vaccines must have caused the transverse myelitis. However, Dr. Shinnar recognized that the article's premise is no longer valid.

> The Court: . . . The comment here, the premise for — the premise that they set out in coming to their conclusion is that we're within the time period within where you would see reactions to vaccines. That premise is no longer valid. As you've even testified yourself. My question to you is how can this particular case study stand as it is currently written?
>
> The Witness: My answer would be that the case study by itself as currently written *cannot stand*. What stands is the theoretical argument I proposed to you earlier —.

Tr. at 120 (emphasis added).

Upon questioning by the court as to what progress has been made since 1977 regarding the association of vaccines and transverse myelitis, and why the literature does not document an association between DPT and transverse myelitis, Dr. Shinnar argued unconvincingly that once a case study has been published reporting a particular medical finding, other physicians treating similar cases would not publish their findings unless they had new clinical evidence or a series of similar findings. Tr. at 118. Dr. Robertson rejected this argument that once a clinical finding has been published that one no longer reports such a finding. Dr. Robertson testified that because of the rareness of the condition, as well as the small number of reported cases, he is of the opinion that clinicians would be eager to report every case describing an association between transverse myelitis and vaccinations. Tr. at 153. Dr. Robertson acknowledged that a single published case study which reported a dramatic and clearly associated cause and effect relationship would carry a great deal of weight but stated that he would not feel comfortable rendering an opinion based on this one particular case study, mainly because of the numerous DPT vaccinations administered over the fifteen year period and the consistent lack of an association in the medical literature between DPT and transverse myelitis. Dr. Robertson testified that over time there should be corroboration regarding this association through additional case reports or textbooks. Tr. at 193. Dr. Robertson testified that because the Whittle authors admitted that the child's transverse myelitis could have occurred by chance, as well as the lack of similar case studies, he was of the opinion that the article did not support a cause and effect relationship. Tr. at 151. Given the invalid premise for the one case study and the logical and persuasive testimony of Dr. Robertson concerning the lack of subsequently published materials, the court finds that Dr. Shinnar is without anecdotes upon which to rely.

The second basis for Dr. Shinnar's causation opinion is that transverse myelitis has been associated with some immunizations, notably smallpox. Tr. at 48. Dr. Shinnar also acknowledged that Dr. Swaiman,[29] a pediatric neurologist, reported a link between the rabies and smallpox vaccines and transverse myelitis, but not the DPT vaccine. Tr. at 100. When asked why the literature does not link DPT in relation with transverse myelitis, Dr. Shinnar opined that this was due to the rarity of the association and lack of comprehensive studies to find more than an anecdotal association. Dr. Shinnar first explained that certain types of reactions are more common with certain types of vaccines and illnesses. Fever is a common reaction following DPT. Secondly, the number of seizures and encephalopathies is recognized to be one in 100,000 to one in 500,000 in association with the DPT vaccine, and therefore these reactions are noted in the literature. Dr. Shinnar argues that transverse myelitis in this age group is twice as rare as encephalopathy and is seen less frequently than the other reactions. Therefore, based on this rarity, one would need a study of at least one million to find more than an anecdotal association, which has not been performed. Thus, this association has not been published.

Dr. Shinnar's opinion was that he did not know why DPT was not linked with transverse myelitis and stated that, personally, it made no sense to him.

> As to why not DPT? Well [transverse myelitis] has been associated with other immunizations. . . . And if you can accept that it can occur from immunization, then it can occur from immunization. It may be less common with DPT than with smallpox immunization. But the notion that it can occur with this immunization and not another would require a set

[29]Pediatric Neurology: Principals and Practice (K. Swaiman 1989).

> of hypothesis that are simply not supported by the medical literature, all of which said that it is more likely with this type but it can occur with others.

Tr. at 48.

Dr. Robertson disagreed with Dr. Shinnar's reasoning that since an association had been shown between transverse myelitis and duck rabies and smallpox vaccines, then one should conclude that an association exists between the OPV and DPT vaccines and transverse myelitis. Tr. at 182. Dr. Robertson explained that the rabies vaccine was a toxic vaccine known to cause neurological problems, one which was transverse myelitis. Dr. Robertson testified that the rabies, as well as the smallpox vaccines, were attenuated live viruses which had the capability of producing more complications than the DPT vaccine. The DPT vaccine is produced with a killed virus.

Once again, Dr. Shinnar offers a theory without support. Dr. Shinnar in effect asks the court to accept, without any medical support whatsoever, anecdotal or studies, the fact that DPT and polio should be associated with transverse myelitis as are the rabies and smallpox vaccines and, that being the case, that in fact DPT and polio can cause and did cause transverse myelitis in this case. Dr. Shinnar's testimony in this regard is one series of "prove me wrong if you can" challenges. However, it is he, as petitioner's expert, that is obligated to offer support. While Dr. Shinnar offers the rare occurrence of injuries from DPT and the need for an impractically large sample size to do a study of DPT reactions as an explanation for the lack of studies, this begs the question of why are there are no anecdotes, case reports, or any literature questioning even the possible relationship between DPT and transverse myelitis. As Dr. Robertson testified, based on the large number of DPT vaccinations administered over the last fifteen years and consistent lack of reports in the

medical literature of a link between the two, he would not be comfortable rendering an opinion given this one case study. **Dr. Shinnar has offered not one shred of medical support beyond the theoretical.** After reviewing Dr. Shinnar's testimony, the court is left with no clue to the answer to Dr. Shinnar's fundamental question "Why not DPT?" Tr. at 48. Unfortunately for petitioner, it was petitioner's burden to provide the answer. **From both the logical and legal standpoint, Dr. Shinnar's theory that all immunizations may be associated with transverse myelitis is unexplained, ill-supported and therefore deficient.**

Lastly, and most incredible in Dr. Shinnar's testimony, is that Dr. Shinnar recognizes but dismisses the alternative and real possibility that Heather suffered from a hyper-immune response to an asymptomatic virus. Dr. Shinnar recognized but dismissed an asymptomatic virus on the basis of statistics taken from the Guillain-Barre model. No effort was made to establish the medical correctness of such an analogy — Dr. Robertson testified against such a comparison. In addition, Dr. Shinnar got into the probabilities game in discounting the viral theory since "fifty percent of the time or less will you be asymptomatic. Of those, in a large chunk of them, you ought to find the titers." Tr. at 95. Therefore, based upon an unproven analogy and unknown medical statistics ("large chunk"), Dr. Shinnar ruled out the asymptomatic viral infection as a causative agent.

The error in Dr. Shinnar's testimony is glaring. Once again, the completely theoretical is chosen over the known, generally accepted cause. **Dr. Shinnar neither produces convincing testimony to rule out what he concedes to be a possible cause** — the asymptomatic virus — nor provides any evidence to point to the DPT or polio vaccine. As stated earlier, Dr. Shinnar testified that:

> If you had nothing else because there was no immunization and you have a kid with a transverse myelitis, you're going to end up after you do a work-up for other things and you don't find anything, saying well, I guess most likely it's post-viral because we know there's an association.

Tr. at 107.

In essence, **Dr. Shinnar points to the vaccines because they were a known event** (of course by definition an asymptomatic virus that was not cultured is unknown). This dubious conclusion in turn is premised on the theory that the DPT or polio vaccine can cause transverse myelitis. As shown above, Dr. Shinnar failed to provide any persuasive medical support for that proposition. **Even if Dr. Shinnar had established the DPT and polio vaccines as "possible" causative agents, the court would still find that petitioner failed to establish that it was more likely than not the vaccines and not an asymptomatic virus that caused Heather's transverse myelitis.** Dr. Shinnar failed to demonstrate a clear nexus between the alleged "possibility" and the actual injury. *See Shepard v. Secretary of HHS*, 25 Cl. Ct. 326, 331 (1992) (sustaining special master's rejection of a causation in-fact argument where the expert failed to link the theory of toxicity to the actual injury suffered in the case.) As the court in the *Agent Orange* case[30] stated "[o]ne need hardly be a doctor of medicine to make the statement that if X is a possible cause of Y, and there is no other cause of Y, X must have caused Y."[31] This form of analysis fails to establish a "logical sequence of cause and effect showing the vaccination was the reason for the injury." *See Grant* at 1148.

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[30] *In Re Agent Orange Products Liability Litigation*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F. 2d 145 (2d Cir. 1987), *cert. denied*, 108 S.Ct. 2898 (1988).

[31] *Id.* at 1238.

Dr. Shinnar's entire analysis is based on an intervening event that theoretically could cause a hyper-immune response. However by **ignoring the recognized possibility of an asymptomatic virus as the causative agent,** and producing no persuasive support for treating the DPT and polio vaccines the same as rabies and smallpox vaccines, **Dr. Shinnar fails to provide** a "reputable medical or scientific explanation" to support his opinion. *See Grant* at 1148. Instead, Dr. Shinnar is relying upon the temporal association of the vaccines to the injury. Such reliance is insufficient proof of causation. *See Hasler* at 205. Although both medical experts were credible and knowledgeable, the court finds that Dr. Shinnar's theory of causation is not supported by any current medical literature, and fails to establish that the DPT vaccine caused Heather's transverse myelitis.

CONCLUSION

Heather McCummings case is a tragic one. However, petitioner has the burden to prove by a preponderance of the evidence that the DPT immunization actually caused Heather's transverse myelitis. Regrettably, this burden has not been met. Congress designed the Vaccine Program to compensate those who can demonstrate a statutory or actual causal link between the vaccination and the injury. The evidence presented in this case fails to establish such a link.

Based on the findings *supra*, the undersigned finds that petitioner is not entitled to compensation. The Clerk of the Court is directed to enter judgment accordingly.

Filed
ILLEGIBLE

Gary J. Golkiewicz

Gary J. Golkiewicz
Chief Special Master

IN THE UNITED STATES CLAIMS COURT

Docket No. 90-903V

Filed: December 23, 1992

FILED
U.S. COURT OF APPEALS
FOR THE FEDERAL CIRCUIT
Date Illegible

LINDA L. McCUMMINGS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent	National Childhood Vaccine Injury Act; Standard of review; Arbitrary and capricious; Burden of proof; Preponderance of the evidence; Transverse myelitis.

Keith W. Donahoe, Washington, D.C. for petitioner.

Caroline F. Gosse, Washington, D.C. for respondent.

OPINION

ROBINSON: Judge.

Introduction

On September 10, 1990, petitioner filed a request for compensation under the National Childhood Vaccine Injury Act (the "Vaccine Act" or the "Act"), 42 U.S.C. §§ 300aa-1 to -34 (19888, *amended by* several public laws (codified as amended at 42 U.S.C.A. §§ 300aa-1 to 34 (West Supp. 1992)), on behalf of her daughter, Heather McCummings. Chief Special Master Gary Golkiewicz concluded, on July 10, 1992, that petitioner was not entitled to compensation under the Act. *McCummings v. Secretary of HHS*, No. 90-903V, 1992 WL 182190 (Cl. Ct. Spec. Mstr. July 10, 1992). This matter is now before the court on petitioner's request

for review of the Chief Special Master's entitlement decision. Petitioner objects to the Chief Special Master's decision on two grounds; 1) the Chief Special Master applied an impermissible burden of proof, and 2) the Chief Special Master improperly weighed the evidence before him.[1] For the following reasons, the court affirms the Chief Special Master's decision.

Background

A. *Medical History.*

Heather McCummings was born on July 21, 1980, after an uncomplicated pregnancy and delivery by Cesarean section. Pet. Ex. B(1) at 5.[2] Heather's physician first examined her on August 4, 1980. At that time, the practitioner told petitioner that Heather was "doing well." During a September 23, 1980 appointment, Heather received her first diphtheria-pertussis-tetanus (DPT) and oral polio vaccine (OPV) vaccinations. Pet. Ex. B(2) at 7-8; Tr. at 13. On February 16, 1981, Heather received her second set of DPT and OPV vaccinations. Pet. Ex. B(2) at 7.

Five days after the second administration of the vaccines, on February 21, 1981, petitioner observed that Heather was

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[1]Petitioner does not dispute that she bore the burden of proof since Heather's injury is an off-Table injury. Heather was diagnosed as having transverse myelitis. Petitioner does not contend that this disease is a Table injury. *See* 42 U.S.C. § 300aa-14(a) & (b). Even if the disease were a Table injury, however, petitioner would still bear the burden of proof, since the injury occurred five days after the inoculations -- beyond the period in which the statute creates a presumption of causation in favor of petitioners. *McCummngs*, slip op. at 1 n.2, 14.

[2]"Pet. Ex." refers to the affidavits and documents filed by petitioner in this matter. "Tr." refers to the official transcript of the hearing held before Chief Special Master Golkiewicz on April 16, 1992.

unable to move her legs or sit up. Pet Ex. B(4) at 23, 24; Pet. Ex. B(5) at 30, 32, 34. Heather was admitted to Hartford Memorial Hosptial on February 23, 1981, with a diagnosis of probable transverse myelitis. Pet. Ex. B(3) at 15. Dr. Douglas Abbott conducted a neurological examination of Heather on the day of her admission. He surmised that she was suffering from transverse myelitis secondary to the vaccinations. He recommended that she be transferred to the University of Maryland Hospital for further evaluation. Pet. Ex. B(4) at 23.

At the hospital, Heather underwent a number of diagnostic examinations. Dr. Margaret Rennels examined Heather for infectious diseases on February 24, 1981. She noted in her files that Heather had experienced a slightly runny nose and a temperature of 100 degrees on February 21. The fact that Heather had received OPV and DPT vaccines five days before the onset of symptoms was "of concern." The doctor also noted that a very small number of polio vaccine recipients develop paralysis, but the typical conditions were different from those Heather suffered. "Other possibilities" for Heather's symptoms included Guillain-Barre and transverse myelitis "which are associated with a number of infections." She recommended serologic tests for several viruses. Pet. Ex. B(5) at 32-33.

Heather was also examined by Dr. Maria Gumbinas on February 24, 1981. Dr. Gumbinas diagnosed Heather as having transverse myelitis, which was already improving. She noted in her records that it was "temporally related to DPT and Polio vaccine[, but she ruled] out direct viral infection with polio, coxackie, ECNO." Pet. Ex. B(5) at 34. According to a May 1981 letter from Dr. Rennels to Dr. Gumbinas, that described the serology titers and viral cultures done on Heather, the immunological workup was normal. Dr. Rennels

also noted that it probably would not be possible to determine either; "1) the etiology of [Heather]'s paresis, or 2) whether or not it was vaccine related." Pet. Ex. B(5) at 48.

Dr. Huang, a pediatric immunologist, was consulted on February 26, 1981. Pet. Ex. B(5) at 37. He observed that it was "prudent to think the paralysis was related" to one of the vaccinations because of the close timing between the immunizations and the onset of the illness. However, in his consultation, he also advised of a UCLA study of 3000 cases of individuals who received DPT or DT vaccinations. In some instances the vaccinations were followed by seizures or "CNS involvement[, but] [n]o case of paralysis was reported." Pet. Ex. B(5) at 37.

As a consequence of the transverse myelitis, Heather underwent two surgeries. She now has decreased movement in her right foot and ankle, and she uses a brace for her foot at night. She is also burdened with performing urinary self-catheterization every four hours.

B. *Expert Testimony.*

At the hearing before Chief Special Master Golkiewicz, on April 16, 1992, petitioner presented the testimony of Dr. Shlomo Shinnar, a board certified neurologist with special competence in child neurology and pediatrics. Dr. Shinnar agreed with the diagnosis of transverse myelitis. Tr. at 33.

Dr. Shinnar explained that transverse myelitis generally occurs in two settings. First, the disease may occur as a hyper-immune response to a variety of agents, such as, a prior viral infection, an antigen in the body, and smallpox immunizations. Second, transverse myelitis may occur as part of an acute viral syndrome, such as, with the Epstein-Barr virus, the mononucleous virus, or the influenza virus. Tr. at 34.

Since the medical records showed "no definitive evidence of an acute viral syndrome," Dr. Shinnar, during his testimony, discounted that possibility as a cause of Heather's transverse myelitis. Tr. at 36-38. Rather, he concluded that it was "more likely than not" that the immunizations, which Heather received five days earlier, caused the transverse myelitis. Tr. at 33-34. Dr. Shinnar explained that transverse myelitis at a young age is "a very rare entity." Thus, he attributed, greater weight to the fact that the inoculations occurred temporally close to the onset of the disease than he would have if the two occurrences were relatively common. Tr. at 47.

Dr. Shinnar continued theorizing that, since rabies and smallpox vaccinations are associated with transverse myelitis in the medical literature, it makes sense, from a medical standpoint, to consider the possibility that another immunization, such as the DPT, could cause the disease. Tr. at 72-73. As support for this conclusion, Dr. Shinnar cited a case study reported in the British Medical Journal.[3]

Respondent's expert, Dr. William Robertson, who is board certified in neurology and pediatrics, agreed with Dr. Shinnar that the diagnosis of transverse myelitis was accurate; however, Dr. Robertson opined to a reasonable degree of medical certainty that Heather's transverse myelitis was caused by a viral infection, not by the immunizations. Tr. at 147. Dr. Robertson testified that he believed Heather's runny nose and low grade fever were symptoms of a virus. Tr. at 149. Although Dr. Robertson admitted that no scientific evidence exists to support the theory that transverse myelitis can be caused by a virus, he believed a causal relationship existed because medical literature documents that a viral infection

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[3]E. Whittle, *Transverse Myelitis after Diphtheria, Tetanus, and Polio Immunisation*, British Medical Journal 1:1450 Vol. 1, June 4, 1977 [hereinafter the Whittle article].

may occur concomitantly with the manifestation of transverse myelitis. Tr. at 161, 175.

Finally, Dr. Robertson disputed Dr. Shinnar's reliance upon the Whittle article for the proposition the DPT or OPV vaccine can cause transverse myelitis. First, he noted that the authors of the article only proposed an association between the vaccines and transverse myelitis; they did not conclude that the vaccines caused the disease. Tr. at 150-51. Second, Dr. Robertson pointed out that the infant, whose case was the subject of the Whittle article, had symptoms which suggested that the child may have had a viral infection prior to or concurrent with her development of transverse myelitis. Tr. at 151.

Contention of the Parties

Petitioner contends that Chief Special Master Golkiewicz applied an impermissible burden of proof, and that he improperly weighed the evidence before him. Respondent argues that petitioner misconstrues both the law governing her evidentiary burden and the Chief Special Master's application of the law to petitioner's case. Respondent adds that the Chief Special Master's decision was reasonable in light of the evidence before him.

DISCUSSION

The Vaccine Act grants the Court of Federal Claims jurisdiction to review the decision of a special master. Before the Act was amended in 1989, the court possessed greater latitude for review than it currently does. It could review findings of fact and conclusions of law made by a special master and make a "de novo determination of any matter." 42 U.S.C. § 300aa-12(d)(1) (1988) (amended 1989). Recent amendments

to the act have limited the court's authority by "preclud[ing] de novo review in the [Court of Federal Claims] of a decision of a special master." *Hale v. Secretary of HHS*, 22 Cl. Ct. 403, 405 (1991).

Under the amended Act, the court may either uphold, remand, or set aside the findings of fact or conclusions of law of a special master. 42 U.S.C. § 300aa-12(e)(2). However, the court may upset such findings and conclusions only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 42 U.S.C. § 300aa-12(e)(2)(B). [The court may then] issue its own findings of fact and conclusions of law." *Id.*

In *Hines ex rel. Sevier v. Secretary of HHS*, 940 F.2d 1518 (Fed. Cir. 1991), the United States Court of Appeals for the Federal Circuit discussed the arbitrary and capricious standard at length, but declined to adopt any exact formulation of the standard for vaccine cases. *Id.* at 1528. It remarked, however, that, regardless of the precise definition, " 'arbitrary and capricious' is a highly deferential standard of review." *Id.* The court explained that "[i]f the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Id.* After carefully considering petitioner's contentions and Chief Special Master Golkiewicz's decision, this court cannot say that the prior decision was arbitrary or capricious; indeed, this court finds the Chief Special Master's decision thorough, articulate, and well-reasoned.

A. *Petitioner's Burden of Proof.*

Petitioner first charges that the Chief Special Master required the incorrect burden of proof from her to substantiate her claim. This court finds no misapplication of the legal standards involved in this action.

Chief Special Master Golkiewicz correctly stated that, under the Vaccine Act, petitioner is required to demonstrate causation-in-fact by a preponderance of the evidence. *McCummings*, slip op. at 14. As he explained, "[t]he burden rests on the petitioner to show that the vaccination . . . more likely than not caused the [transverse myelitis], under the same standards which apply in traditional tort litigation." *Id.* at 14 (citing *Hines* at 1525).

In *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992), the Federal Circuit discussed the burden which the petitioner faces in proving causation-in-fact:

> [P]etitioner must show a medical theory causally connecting the vaccination and the injury. . . .[This] requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Id. at 1148 (citations omitted).

The Chief Special Master expressly recognized that this case is one of first impression since "there are no epidemiological studies or other hard medical evidence to prove or disprove the cause of transverse myelitis in children." *McCummings*, slip op. at 15. Thus, he concluded that it falls "squarely within the parameters" set in *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), a case involving the novel causation issue of whether paraquat, a toxic herbicide, causes pulmonary fibrosis. There being no generally accepted theory of causation for transverse myelitis in children, the Chief Special Master followed *Ferebee* and decided this case by "looking at the expert's reasoning, how the limited medical information supports that reasoning, and

whether the reasoning is logically sound and in accordance with generally accepted medical practice." *McCummings*, slip op. at 18-19.

Petitioner claims that, in spite of the Chief Special Master's language, he required petitioner to prove her case to the degree of a medical certainty. Petitioner confuses the Chief Special Master's use of "medical certainty" with his use of "preponderance of the evidence." Although the court understands petitioner's confusion, the court, nevertheless, finds that the Chief Special Master imposed the correct burden of proof on petitioner — preponderance of the evidence.

The phrase "reasonable degree of medical certainty" relates to a medical expert's opinion. It can refer to the expert's level of confidence in the opinion, or the phrase can refer to the weight or credibility the finder of fact allocates to the expert's opinion. This court is convinced that Chief Special Master Golkiewicz's discussion of Dr. Shinnar's testimony, as is highlighted above, reveals, not that the Chief Special Master required petitioner to prove her case to a medical certainty, but that the Chief Special Master was skeptical of Dr. Shinnar's theory of causation. The Chief Special Master's application of the standard of "preponderance of the evidence" to petitioner's case as a whole, including Dr. Shinnar's testimony, is evident and proper.

B. *Chief Special Master's Consideration of The Evidence.*

Petitioner next contends that the Chief Special Master improperly weighed the evidence before him. This court finds to the contrary.

The manner in which a special master weighs the evidence to reach his conclusion, however, is subject to deference by the reviewing court. The review standard legislated in

42 U.S.C. §300aa-13(b)(1) encapsulates the longstanding rule evolved in case law "that an expert opinion, even uncontroverted, is not binding on the trier of fact." *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400, 403 (1991). "[T]he proper discharge of the fact-finding function requires that the truth of the testimony offered be evaluated not only in terms of a witness' demeanor but also by the probative force of attendant circumstances." *Bradley v. Secretary of HHS*, 24 Cl. Ct. 641, 644 (1991).

Chief Special Master Golkiewicz carefully considered the expert testimony from Dr. Shinnar, for petitioner, and Dr. Robertson, for respondent. The Chief Special Master weighed each element of Dr. Shinnar's conclusion that Heather's transverse myelitis was caused by the DPT vaccine. *McCummings*, slip op. at 5-11. He discussed in detail the three bases for Dr. Shinnar's conclusion: 1) anecdotal reports in the Whittle article that linked the vaccine with the disease; 2) the absence of proof that the vaccines could not cause the disease; and 3) the lack of evidence that a viral infection caused the disease. *Id.* at 20-25.

When questioned by the Chief Special Master about the lack of medical literature, other than the Whittle article, suggesting a link between the vaccinations (the DPT vaccination in particular) and transverse myelitis, Dr. Shinnar answered that after publication of a few cases linking the vaccinations to the disease, other reports would be published only if they documented a series of such associations or present a new piece of evidence. Tr. 118. Dr. Robertson countered, that, given the rareness of transverse myelitis and the small number of reported cases, clinicians would "be anxious to report every case." Tr. at 152-53. Thus, Dr. Robertson stated, if a cause and effect relationship actually exists between the vaccines

and transverse myelitis, he would expect corroboration of the association in medical textbooks or that additional cases would be reported. Tr. at 193.

Further questioning of Dr. Shinnar revealed that even the basic premise of the Whittle article, "that the transverse myelitis occurred during the time frame one would expect to see reactions to immunizations[,] . . . is no longer valid." Tr. at 120. The Chief Special Master found that, because the premise of the case study in the Whittle article was invalid and he was persuaded by Dr. Robertson's testimony, "Dr. Shinnar is without anecdotes upon which to rely." *McCummings*, slip op. at 21. The Chief Special Master drew a plausible inference from the evidence before him.

Dr. Shinnar's second point, that since transverse myelitis is associated with some immunizations it should be linked with others, is likewise not well-supported in the literature. Dr. Shinnar dismissed this paucity because 1) the disease is rare, and 2) there is a lack of comprehensive studies investigating the connection between the disease and the DPT vaccination. Dr. Shinnar concluded, "[Y]ou would not expect in studies of certainly less than a million and maybe even more to find more than an anecdotal association." Tr. at 54.

Chief Special Master Golkiewicz drew a different, but entirely plausible, inference from the lack of support in the medical literature for Dr. Shinnar's theory — that there is no well-documented link between the disease and the OPV or DPT vaccinations. The Chief Special Master concluded:

> [The lack of studies] begs the question of why are [sic] there are no anecdotes, case reports, or any literature questioning even the possible relationship between DPT and transverse myelitis . . . . From both the logical and legal standpoint, Dr. Shinnar's

> theory that all immunizations may be associated with transverse myelitis is unexplained, ill-supported and therefore deficient."

McCummings, slip op. at 23.

The Chief Special Master found further fault with Dr. Shinnar's conclusion because the expert dismissed the possibility that an asymptomatic virus had caused the disease. *McCummings*, slip op. at 23. Dr. Shinnar arrived at this result on the basis of statistics taken from the Guillain-Barre model, but he made no effort to establish the "medical correctness of such an analogy" to transverse myelitis. *Id.* at 23-24. Accordingly, the Chief Special Master concluded that "Dr. Shinnar neither produce[d] convincing testimony to rule out what he concede[d] to be a possible cause — the asymptomatic virus — nor provide[d] any evidence to point to the DPT or polio vaccine." *Id.* at 24. The Chief Special Master did not, as petitioner contends, require Dr. Shinnar to disprove the possibility of an asymptomatic virus as the cause of the transverse myelitis.[4] Rather, the Chief Special Master found that Dr. Shinnar dismissed the possibility of this cause, without showing that it merited such dismissal. *Id.* Therefore, the Chief Special Master concluded that "Dr. Shinnar fail[ed] to provide a 'reputable medical or scientific explanation.' " *Id.* at 25 (quoting *Grant* at 1148).

Finally, the Chief Special Master found Dr. Shinnar's opinion insufficient to establish that the vaccines caused Heather's transverse myelitis. *Id.* The Chief Special Master determined that Dr. Shinnar's reasoning was flawed by his over-reliance on the temporal association between the DPT vaccin-

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[4]Petitioner contends that this is patently unfair because an asymptomatic virus, by definition, occurs without symptoms.

ation and the injury: "Dr. Shinnar's entire analysis is based on an intervening event that theoretically could cause a hyper-immune response." *McCummings*, slip op. at 25. Numerous cases have rejected an exclusive reliance on temporal associations. *E.g., Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("Temporal association is not sufficient . . . to establish causation in fact."); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) ("[W]ithout more, [a] proximate temporal relationship will not support a finding of causation."), *cert. denied*, 469 U.S. 817 (1984); *Strother v. Secretary of HHS*, 18 Cl. Ct. 816, 820 (1989) ("Temporal association of the onset of injury with the vaccine is not sufficient . . . to establish causation in fact.") Although the Chief Special Master, here, found that petitioner's expert witness was credible and knowledgeable, he concluded that "Dr. Shinnar's theory of causation [was] not supported by any current medical literature, and fail[ed] to establish that the DPT vaccine caused Heather's transverse myelitis." *McCummings*, slip op. at 25. This court finds that the Chief Special Master properly weighed the evidence in reaching these conclusions.

CONCLUSION

Chief Special Master Golkiewicz found that petitioner was unable to demonstrate that the vaccinations caused Heather's transverse myelitis. Once he found that petitioner failed to meet her burden of proof, the Chief Special Master did not need to, and did not, determine what did cause the disease in this case. This result is not surprising given that physicians have yet to solve the mystery of what causes transverse myelitis in infants. The court will not attempt to solve the mystery either. This court need only find that the Chief Special Master's decision was not arbitrary or capricious, that the Chief Special Master did not abuse his discretion, and that

the decision was otherwise in accordance with the law. The court so finds; the decision of the Chief Special Master is affirmed.

/s/ Wilkes C. Robinson

WILKES C. ROBINSON, Judge

United States Court of Appeals
for the Federal Circuit

RECEIVED
NOV 24, 1993

OPINION ANNOUNCING JUDGMENT OF THE COURT

OPINION FILED AND JUDGMENT ENTERED:
November 23, 1993

The attached opinion announcing the judgment of the court in your case was filed today. The judgment was entered pursuant to Rule 36. The mandate will be issued in due course.

Costs are taxed against the Petitioner(s) in favor of the Respondent(s) under Rule 39. The party entitled to costs is provided a bill of costs form and an instruction sheet with this notice.

The parties are encouraged to stipulate to the costs. A bill of costs will be presumed correct in the absence of a timely filed objection.

Costs are payable to the party awarded costs. If costs are awarded to the government, they should be paid to the Treasurer of the United States. Payment should be made to counsel for the party awarded costs or, if the party is not represented by counsel, to the party pro se. Payment of costs should not be sent to the court. Costs should be paid promptly.

If the court also imposed monetary sanctions, they are payable to the opposing party unless the court's opinion provides otherwise. Sanctions should be paid in the same way as costs.

Exhibits and visual aids shall be promptly retrieved by the party that lodged them with this court.

FRANCIS X. GINDHART
Clerk

cc: KEITH W. DONAHOE
CAROLINE GOSSE ELMENDORF

MCCUMMINGS V HHS, 93-5081
(CFC - 90-903V)

NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record. The disposition will appear in tables published periodically.

United States Court of Appeals
for the Federal Circuit

93-5081

LINDA L. MCCUMINGS,
Petitioner-Appellant,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

DECIDED: November 23, 1993

Before RICH and ARCHER, *Circuit Judges*, and LAY, *Senior Circuit Judge*.*

LAY, Senior Circuit Judge.

DECISION

This is an appeal brought under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to - 34 (1988), *amended by* several public laws. It is brought by Linda L. McCummings, petitioner against the Secretary of the Department of Health and Human Services on behalf of her daughter, Heather McCummings. The trial was held before a Chief Special Master, Gary Golkiewicz, who denied compensation under the Act. This was appealed to the United States Claims Court

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*Honorable Donald P. Lay, Senior Circuit Judge, United States Court of Appeals for the Eighth Circuit, sitting by designation.

where Judge Wilkes C. Robinson affirmed the Special Master's decision. Further appeal was brought to this court. We *affirm*.

DISCUSSION

Petitioner urges, as she did before Judge Robinson, that an order for compensation is warranted, first because the Chief Special Master applied an impermissible burden of proof, and second, because he failed to properly weigh all of the evidence before him.

Heather McCummings was born on July 21, 1980. There were no complications in her delivery by cesarean section. Heather received vaccinations for diphtheria pertussis-tetanus (DPT) and oral polio vaccine (OPV) on September 23, 1980, and on February 16, 1981. Five days after receiving the second set of vaccines, she showed signs of paralysis, and on February 23, she was diagnosed as having probable transverse myelitis secondary to her vaccinations. She was transferred to the University of Maryland Hospital. Dr. Margaret Rennels made a diagnosis that it was not possible to determine either "1) the etiology of [Heather]'s paresis, or 2) whether or not it was vaccine related." Dr. Huang, a pediatric immunologist, was consulted and opined that it was "prudent to think the paralysis was related" to one of the vaccinations because of the temporal relationship between the illness and the vaccinations. He reported a study, however, which found no cases of paralysis resulting from the vaccines. At the hearing, Dr. Shlomo Shinnar, a board certified neurologist, testified that Heather was suffering from transverse myelitis. He concluded that it was "more likely than not " that the vaccinations caused the transverse myelitis. The Secretary produced an expert witness, Dr. William Robertson, who was board certified in both neurology and pediatrics. He agreed with the diagnosis of transverse myelitis but reasoned that it was caused

by a viral infection and not the immunizations.

Judge Robinson, in affirming the Special Master's findings, held that he could only upset such findings and conclusions if they were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). Judge Robinson found the Special Master's opinion was "thorough, articulate, and well reasoned."

On this appeal, as well as before the Claims Court, petitioner urges that the Special Master required petitioner (1) to support her theory of causation by medical or scientific studies, and (2) to exclude all other possible causes.

Judge Robinson analyzed petitioner's claims and responded:

> [T]he Chief Special Master concluded that "Dr. Shinnar neither produce[d] convincing testimony to rule out what he concede[d] to be a possible cause — the asymptomatic virus — nor provide[d] any evidence to point to the DPT or polio vaccine." The Chief Special Master did not, as petitioner contends, require Dr. Shinnar to disprove the possibility of an asymptomatic virus as the cause of the transverse myelitis. Rather, the Chief Special Master found that Dr. Shinnar dismissed the possibility of this cause, without showing that it merited such dismissal. Therefore, the Chief Special Master concluded that "Dr. Shinnar fail[ed] to provide a 'reputable medical or scientific explanation.' " (quoting *Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).
>
> Finally, the Chief Special Master found Dr. Shinnar's opinion insufficient to establish that the vaccines caused Heather's transverse myelitis. The

> Chief Special Master determined that Dr. Shinnar's reasoning was flawed by his overreliance on the temporal association between the DPT vaccination and the injury: "Dr. Shinnar's entire analysis is based on an intervening event that theoretically could cause a hyper-immune response." Numerous cases have rejected an exclusive reliance on temporal associations. *E.g., Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("Temporal association is not sufficient . . . to establish causation in fact."); *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) ("[W]ithout more, [a] proximate temporal relationship will not support a finding of causation."), *cert. denied*, 469 U.S. 817 (1984); *Strother v. Secretary of HHS*, 18 Cl.Ct. 816, 820 (1989) ("Temporal association of the onset of injury with the vaccine is not sufficient . . . to establish causation in fact."). Although the Chief Special Master, here, found that petitioner's expert witness was credible and knowledgeable, he concluded that "Dr. Shinnar's theory of causation [was] not supported by any current medical literature, and fail[ed] to establish that the DPT vaccine caused Heather's transverse myelitis." This court finds that the Chief Special Master properly weighed the evidence in reaching these conclusions.

McCummings v. Secretary of Health & Human Servs., 27 Fed. Cl. 417, 422 (Cl. Ct. 1992) (citations to Chief Special Master's opinion omitted).

This case is indeed an unfortunate one. There is in this record medical evidence that supports both theories of causation. However, a trier of fact has the opportunity to judge the credibility of the various experts and to then weight the per-

suasiveness of their opinions. In this case, the Chief Special Master found that the government's expert witness was more persuasive than petitioner's. The Chief Special Master set forth his reasons for reaching this determination. We likewise find that the Claims Court properly determined that the Chief Special Master did not misapply the burden of proof. As an appellate court, we lack the authority to make findings of fact de novo. We can only reverse the Special Master if we find that the United States Claims Court erred in its assessment. We find no error here.